



UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Tuesday, July 16, 2013

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 79814-L
Product Name: FruitGard
DP Barcode: D412521
Decision No: 470317
Action Code: A540
PC Code: 020502

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

IB

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

*Chris Jiang 7/18/13
for KPM*

To: Demson Fuller, Acting PM 32/ David Liem
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: ICA Trinova, LLC

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
020502	Sodium Chlorite	3.2
	<u>Other Ingredient(s):</u>	<u>96.8</u>
	Total:	100.0

- I. Background Information: The Chemistry and Toxicology Team (CTT) conducted an acute toxicology review of EPA File Symbol 79814-L on 2/12/2013. CTT considered that submission by ICA Trinova, LLC, to be incomplete. The results of that review were:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	48958004	IV	Acceptable
Acute Dermal Toxicity	None	?	Waiver Denied
Acute Inhalation Toxicity	42484101	II	Cited
Primary Eye Irritation	None	?	Waiver Denied
Primary Skin Irritation	None	?	Waiver Denied
Dermal Sensitization	None	?	Waiver Denied

In June, 2013, CTT has received a follow-up submission for 79814-L. This submission included:

- An acute dermal toxicity study, a primary eye irritation study, a primary skin irritation study and a dermal sensitization study.
- An application summary with administrative materials. This includes a discussion of the acute toxicity profile of the four new studies, copies of CTT's prior product chemistry and acute toxicity reviews, and, proposed labels of 79814-L.

II. Findings: Each of the four submitted studies is acceptable.

III. Precautionary Labeling: Label Review System

PRODUCT ID #: 079814-00005

PRODUCT NAME: FruitGard

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

SPANISH SIGNAL WORD: AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

May be fatal if inhaled. Causes moderate eye irritation. Do not breathe dust or gas. Avoid contact with eyes or clothing. Wear protective eyewear. For handling activities, use a non-powered air purifying respirator equipped with an N-, R-, or P-series filter. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and chemical-resistant gloves (such as Barrier Laminate, Butyl Rubber, Selection Category B). Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Label Created by: Ian Blackwell on 07/16/2013 Last Updated by: Ian Blackwell on 07/16/2013

DATA EVALUATION RECORD

Product Reg. No.: 79814-L

Product Name: FruitGard

1. DP BARCODE: D412521

2. PC CODE: 020502

3. CURRENT DATE: 07/15/13

Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Grade
Acute oral toxicity / rat / Stillmeadow/ 13978-10 / 9- 10-10	48958004	LD ₅₀ > 5,000 mg/kg b.w.	IV	A
Acute dermal toxicity/ rat / Product Safety Labs / 36249/ 5-6-2013	49120901	LD ₅₀ > 5,000 mg/kg b.w.	IV	A
Acute inhalation toxicity / rat / 2006 RED	None		II	C
Primary eye irritation / rabbit / Product Safety Labs/ 36250 / 5-6-2013	49120902	Corneal opacity in 2/3 @ 24 hrs. No iritis. Mild to moderate redness. Mildly irritating to eyes.	III	A
Primary dermal irritation / rabbit / Product Safety Labs/ 36251 / 5-6-2013	49120903	Very slight erythema in 3/3 @ 72 hrs. No edema. Some desquamation.	IV	A
Dermal sensitization / LLNA / mice / Product Safety Labs / 36252 / 5-6- 2013	49120904	Dermal sensitizer	---	A

Grade Key: A =Acceptable, U = Unacceptable, D = Data Gap